

Roundtable Discussion Questions

Guided by a Professional Facilitator

Informed by the plenary presentations and discussions in the first day of the conference, Roundtable members will be asked to consider a series of questions concerning the expectations, roles and responsibilities associated with IBCs. This discussion will be guided by a professional facilitator to ensure full development of the issues that arise. At the end of this discussion, Roundtable members will consider a series of case studies that will allow them to consider their views about IBCs in the context of concrete examples. The case studies entail “Modified Scenarios” that change key considerations to test whether Roundtable member views are dependent on specific conditions. Finally, the Roundtable will consider how the key roles and essential responsibilities of IBCs are reflected in the *NIH Guidelines*.

Some characteristics and questions to be explored include:

1. Exploration of Specific Characteristics of IBCs

a. Accountability

- i. In what ways are IBCs accountable to institutions for their performance?
- ii. In what ways are institutions accountable for the quality of IBC compliance, reviews, and decisions?
- iii. How are institutions and investigators made responsive to IBC decisions and concerns?
- iv. How do institutions ensure that IBCs have access to necessary institutional records? Must the IBC be physically present at the institution for such access to occur?
- v. What kind of institutional representation, if any, is necessary on the IBC for it to be effective?

b. Accessibility/Availability

- i. Public access to IBC meetings is encouraged by the *NIH Guidelines*. How important is public access? Should it be mandated? How can it be achieved under various IBC arrangements?
- ii. Do IBCs typically make themselves available as a resource to investigators and other institutional staff? If so, in what ways?

c. Community concerns

- i. What perspectives should non-institutional members bring to IBC discussions? Environmental? Public safety and health? Community ethos? Others?
- ii. Is it important to have non-scientific community perspectives on the IBC? Why?
- iii. What is the “community” for purposes of IBC review? (Same town? 50-mile radius? Same state?)

- iv. Should “community” have a non-geographic meaning in the context of IBC membership (encompassing certain patient groups, ethnicities, or other classes of people who might be subjects)?
 - v. To what degree, and how, are IBCs accountable to the community?
 - d. Safety surveillance**
 - i. What is the role of the IBC with regard to safety surveillance?
 - ii. Must members of the IBC be physically present to carry out surveillance of safety concerns?
 - iii. When biosafety problems arise, how should IBCs respond?
 - e. Containment/facilities**
 - i. How important is on-site knowledge of procedures, physical plant, and facilities to IBCs assessments of containment?
 - ii. Are institutional employees better poised to assess safety, risk, and containment issues than outsiders who may periodically conduct site visits?
 - iii. Should other local characteristics be taken into account during this assessment (laboratory staffing, equipment, training, etc.)?
 - f. Local knowledge**
 - i. How important is knowledge of investigators and other local circumstances to the quality of IBC review? Could knowledge of investigators bias review?
 - g. Training**
 - i. In what ways do IBCs assess the training of investigators and others who may handle recombinant materials?
 - ii. In what ways do IBCs promote the training of investigators and laboratory staff?
 - h. Other characteristics**
 - i. What other characteristics of IBCs may be important for ensuring their competency?
- 2. Case discussions** – Roundtable and audience members will be asked to consider the characteristics just discussed in the context of some case scenarios. The scenarios are fictionalized, but are based on actual or proposed IBC arrangements of which OBA is aware. Each case will entail modified scenarios that will change key considerations to test whether views are dependent on specific conditions.
- 3. The NIH Guidelines and IBCs** – Having worked through the preceding exercises, Roundtable and audience members will be asked for their views about the following question: *In light of the changing research landscape, what do the day’s discussions suggest for how the key roles and essential responsibilities of IBCs are reflected in the NIH Guidelines?*